AUG 21 2003

K030367

C. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

[in Accordance with SMDA of 1990]

Columbus Total Knee System (PS)

February 4, 2003

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

Establishment Registration Number: 2916714

CONTACT: Joyce Kilroy
800/258-1946 x 5074 (phone)
610/791-6882 (fax)

TRADE NAME: Columbus (PS)

COMMON NAME: Columbus Total Knee System (PS)

DEVICE CLASS: Class II

PRODUCT CODE: **87 JWH**

CLASSIFICATION: 888.3560 – Prosthesis, Knee, Patellofemortibial Semi-constrained, Cemented, polymer/metal/polymer

REVIEW PANEL: Orthopedics

INDICATIONS FOR USE

The Columbus Total Knee System (PS) is indicated for use in reconstruction of the diseased knee joint caused by osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, the need to revise failed arthroplasties or osteotomies where pain, deformity or dysfunction persist, and for patients suffering from correctable valgus or varus deformity and moderate flexion contracture.

Posterior Stabilized (PS) components are also for absent or non-functioning posterior cruciate ligament and severe anteroposterior instability of the knee joint.

The Columbus Knee (PS) is designed for use with bone cement.

DEVICE DESCRIPTION

The cemented Columbus Knee System (PS) is available with one femoral design, the Posterior Stabilizing (PS) which offers stabilization if the ligament (PCL) is absent, weakened or sacrificed during implantation. The design of the femoral component, and tibial plateau (tray) are manufactured from CoCrMo. The tibial "gliding surfaces" (inserts) and patellas are manufactured from UHMWPE.

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PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) for Cemented, Semi-constrained Total Knee Prostheses" were completed. Biomechanical testing results demonstrate the Columbus Knee System is substantially equivalent to other knee systems currently on the market.

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the Columbus Total Knee System is substantially equivalent to:

- Search Evolution Total Knee System (K021313)
- Scorpio PS Knee System (K962152)
- Scorpio Total Stabilizer (K0994128)
- Gem Knee System (K994214)
- Gem PS Total Knee System (K010101)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 2003

Ms. Joyce Kilroy
Director of Regulatory Affairs and Quality Assurance
Aesculap Incorporated
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K030367
Trade/Device Name: Columbus Total Knee System (PS)
Regulation Numbers: 21 CFR 888.3560
Regulation Names: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: June 4, 2003
Received: June 5, 2003

Dear Ms. Kilroy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Milhern

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE STATEMENT

510(k) Number: K030367

Device Name: **Columbus Total Knee System (PS)**

Indication for Use:

The Columbus Total Knee System (PS) is indicated for use in reconstruction of the diseased knee joint caused by osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, the need to revise failed arthroplasties or osteotomies where pain, deformity or dysfunction persist, and for patients suffering from correctable valgus or varus deformity and moderate flexion contracture.

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The Columbus Knee (PS) is designed to for use with bone cement.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030367

Prescription Use _____ or Over-the-Counter Use _____

(per 21 CFR 801.109)